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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,909	01/08/2007	Joel Barry Baseman	9237-10	9089
	7590 09/29/200 L SIBLEY & SAJOVE	EXAMINER		
PO BOX 37428			DEVI, SARVAMANGALA J N	
RALEIGH, NC 27627			ART UNIT	PAPER NUMBER
			1645	
			MAIL DATE	DELIVERY MODE
			09/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
Office Action Comments	10/573,909	BASEMAN ET AL.				
Office Action Summary	Examiner	Art Unit				
	S. Devi, Ph.D.	1645				
The MAILING DATE of this communication apperiod for Reply	pears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠ Responsive to communication(s) filed on <i>08 J</i>	anuary 2007					
	s action is non-final.					
3) Since this application is in condition for allowa		secution as to the merits is				
· ·	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
·	ulia akia u					
	4) Claim(s) 1-7 and 9-32 is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6) Claim(s) is/are rejected.						
•	7) Claim(s) is/are objected to.					
8) Claim(s) <u>1-7 and 9-32</u> are subject to restriction and/or election requirement.						
Application Papers						
9)☐ The specification is objected to by the Examiner.						
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date	4)  Interview Summary Paper No(s)/Mail Da 5)  Notice of Informal P 6)  Other:	ite				

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## Lack of Unity

Claims 8 and 33-45 have been canceled.Claims 1-7 and 9-32 are under prosecution.

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

- 3) As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
  - (1) A product and a process specially adapted for the manufacture of said product; or
  - (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

**4)** Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

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In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1, 2, 9 and 10, drawn to an isolated polypeptide comprising an amino acid sequence of SEQ IDNO: 2, 3, 4, 5 or 6, or a biologically active fragment thereof.
- II. Claims 3-5 and 11-13, drawn to an isolated nucleic acid encoding a polypeptide comprising an amino acid sequence of SEQ ID NO: 2, 3, 4, 5 or 6, or a biologically active fragment thereof.
- III. Claims 6, 7, 14 and 15, drawn to an antibody specific to a polypeptide comprising an amino acid sequence of SEQ ID NO: 2, 3, 4, 5 or 6, or a biologically active fragment thereof.
- IV. Claims 16 and 17, drawn to a method of diagnosing *Mycoplasma pneumoniae* infection comprising contacting a sample with the polypeptide or the fragment of invention I.
- V. Claims 18 and 19, drawn to a method of diagnosing *Mycoplasma pneumoniae* infection comprising contacting a sample with the antibody of invention III.
- VI. Claim 20, drawn to a method of diagnosing *Mycoplasma pneumoniae* infection comprising contacting a sample with the nucleic acid of invention II.
- VII. Claims 22, 23, 28 and 29, drawn to a method of eliciting an immune response comprising administering the polypeptide of invention I.
- VIII. Claims 24, 25 and 30, drawn to a method of eliciting an immune response comprising administering the nucleic acid of invention II.
- IX. Claims 26, 27, 31 and 32, drawn to a method of eliciting an immune response comprising administering the antibody of invention III.
- 5) Inventions I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. The special technical feature of the first claimed invention is an isolated polypeptide comprising an amino acid sequence of SEQ IDNO: 2, 3, 4, 5 or 6, or a biologically

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active fragment thereof. However, such a polypeptide or a biologically active fragment thereof was already disclosed in the art at the time of the invention. For example, WO 02/079242 A2 (CHIRON SPA – Applicants' IDS) disclosed an isolated polypeptide comprising the amino acid sequence of SEQ ID N: 4, AAE29374, and/or a biologically active fragment thereof (see pages 2-4 under Sequence Listing). Therefore, the special technical feature of invention I does not define over the prior art. Although the product of invention I, and the first method of using the product of invention IV is a permitted combination under PCT Rule 13.2, in the instant case, since the product of invention I is already disclosed in the art, the special technical feature is not a unifying feature. The special technical features of inventions II-IX are delineated above. The nucleic acid of invention II and the antibody of invention III do not share a significant common structure with the polypeptide of invention I. The methods of inventions IV-IX do not share significant methods steps and parameters, method objectives, products or reagents used, and/or ultimate goals accomplished.

6) The Office has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder*. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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November 15, 1989.

Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30,

Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.Mov">http://pair-direct.uspto.Mov</a>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA and CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/ S. Devi, Ph.D. Primary Examiner AU 1645

September, 2008